IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

KAREN STEVENS, Individually and as Mother, Guardian and Next Friend of MADDY OLIVIA STEVENS and FENNER ZIMBLE STEVENS, Minors,

Plaintiffs,

CIVIL ACTION No. 03-CV-12346 (PBS)

v.

ELI LILLY AND COMPANY,

Defendant.

DEFENDANT ELI LILLY AND COMPANY'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT

INTRODUCTION

Defendant Eli Lilly and Company ("Lilly") moves for partial summary judgment under Fed. R. Civ. P. 56 on all claims asserted by Fenner Zimble Stevens and Maddy Olivia Stevens ("Minor Plaintiffs"). Minor Plaintiffs allege that their claimed injuries are the result of Karen Stevens' ("Ms. Stevens") in utero exposure to Lilly's diethylstilbestrol. Massachusetts law, however, has not recognized, and in all likelihood, will not recognize "third generation" product liability suits sounding in tort. In the context of "pre-conception torts" -- where the plaintiff is claiming injury from tortious action taken before his or her conception -- Massachusetts courts have expressed concern about their ability to sensibly analyze the concepts of duty, foreseeability, and causation. This concern is heightened in the context of "third generation" claims where a plaintiff's claimed injury is one step further removed from the tortious action that allegedly caused it. Further, every appellate jurisdiction that has squarely faced third generation

DES claims have rejected them, based on the same policy considerations cited by Massachusetts courts. Minor Plaintiffs' third generation claims are simply not cognizable in Massachusetts.

DEFENDANT ELI LILLY AND COMPANY'S STATEMENT OF MATERIAL FACTS AS TO WHICH THERE IS NO GENUINE ISSUE¹

Α. **Background Facts**

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- 1. In the Complaint, Ms. Stevens alleges negligence, strict liability, breach of warranty and misrepresentation; Minor Plaintiffs allege negligence and strict liability. Complaint ¶¶ 7-34 (copy attached as Exhibit 1 to Affidavit of Brian L. Henninger ("Henninger Aff.")). All Plaintiffs are seeking punitive damages. *Id.* at ¶ 35.
- 2. Plaintiff's mother, Sondra Zimble ("Ms. Zimble"), became pregnant with Plaintiff in December 1965 while she was living in Natick, MA. See id. at ¶ 7 (Henninger Aff.) (alleging exposure in Massachusetts); Plaintiff Karen Stevens' Answers to Lilly's First Set of Interrogatories ("Interrog.") at Nos. 5(c), 12(a) (copy attached as Exhibit 2 to Henninger Aff.) (stating that the approximate date and place of Ms. Stevens' conception). Ms. Stevens was born on August 29, 1966 in Massachusetts. *Id.* at No. 12(a).
- 3. Ms. Stevens became pregnant with Fenner Stevens in January. *Id.* at Nos. 2(c), 15(a). Fenner was born at 32 weeks gestation on August 27, 1999. *Id.* at No. 15(a).
- 4. Ms. Stevens became pregnant with Maddy Stevens in September. *Id.* at Nos. 2(a). 15(b). Maddy was born at 25 weeks gestation on June 2, 2001. *Id.* at 15(b).

В. Undisputed Facts Relevant to Minor Plaintiffs' Third Generation Claims

5. Ms. Stevens allegedly was exposed to diethylstilbestrol in 1965 and 1966 in Massachusetts. Complaint at ¶ 9 (Henninger Aff., Ex. 1). Fenner and Maddy Stevens were not

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Lilly accepts these facts as undisputed for purposes of this summary judgment motion only and reserves the right to contest any of these facts at trial.

conceived until January 1999 and September 2001 respectively. Interrog. at No. 15(a)-(b) (Henninger Aff., Ex. 2)

6. The claimed injuries of the minor children, Fenner and Maddy Stevens, arise from their premature births; the alleged cause of their prematurity was Ms. Stevens' in utero exposure to DES. See Complaint at ¶ 26 (Henninger Aff., Ex. 1) (stating allegations of Minor Plaintiffs).

ARGUMENT

T. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); Carroll v. Xerox Corp., 294 F.3d 231, 236-37 (1st Cir. 2002). Once a defendant demonstrates the insufficiency of the evidence supporting plaintiff's case, plaintiff must present facts showing a genuine issue for trial. See Carroll, 294 F.3d at 236.

II. LILLY IS ENTITLED TO PARTIAL SUMMARY JUDGMENT AS TO MINOR PLAINTIFFS' CLAIMS BECAUSE MASSACHUSETTS DOES NOT RECOGNIZE THIRD GENERATION CLAIMS.

Minor Plaintiffs Fenner and Maddy Stevens have not alleged a cognizable cause of action in Massachusetts. A thorough review of Massachusetts case law reveals that no court in the Commonwealth has ever recognized "third generation" claims. Furthermore, it is highly unlikely that Massachusetts would recognize a third-generation DES cause of action. Massachusetts courts have considered the viability of preconception torts several times and rejected such causes of action. Moreover, every appellate jurisdiction that has squarely considered the viability of

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² In opposing a motion for summary judgment, a plaintiff must proffer admissible evidence that could be accepted by a rational trier of fact as sufficient to establish the necessary proposition. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). The admissibility of evidence is a procedural matter governed in the federal courts by the Federal Rules of Evidence. See Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 825 n.9 (D.C. Cir. 1988).

third-generation DES claims has rejected them, based on the same policy considerations that Massachusetts has endorsed.

Every Appellate Jurisdiction That Has Squarely Addressed Third A. Generation DES Claims Has Denied A Cause of Action.

Massachusetts courts have never recognized a third-generation DES claim, or any claim in which the plaintiff was not exposed to the defendant's product or even conceived when the alleged tortious conduct occurred. In fact, Massachusetts appellate and federal courts have considered preconception tort claims and rejected them. Claims that wrongful acts done before the plaintiff was conceived caused harm to the plaintiff have been rejected on policy grounds. See Lareau v. Page, 840 F. Supp. 920, 930 (D. Mass. 1993) (aff'd by Lareau v. Page, 39 F.3d 384 (1st Cir. 1994) (rejecting a loss of consortium claim by a daughter who was conceived after her mother was injured); Angelini v. OMD Corp., 575 N.E.2d 41, 43 (Mass. 1991) (rejecting loss of consortium claims for children conceived after parent was injured); see also McNulty v. McDowell, 613 N.E.2d 904 (Mass. 1993) (declining to recognize a cause of action based on failure to administer a rubella test to the plaintiff's mother before plaintiff was conceived).

Moreover, there is no basis to believe Massachusetts would depart from the overwhelming rejection of third-generation DES claims by other appellate courts. To date, five appellate jurisdictions have squarely addressed third generation claims in the DES context,³ and all five have refused to let the claims go forward. See Wood v. Eli Lilly & Co., 38 F.3d 510, 513-14 (10th Cir. 1994) (affirming grant of summary judgment to manufacturers and distinguishing third generation from second generation DES cases because "there is less certainty that a known

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³ In addition, two federal district courts have considered third generation DES claims and rejected them. See Sorrells v. Eli Lilly & Co., 737 F. Supp. 678 (D.D.C. 1990) (construing Maryland law to impose no duty to the unborn grandchild of a woman who ingested DES); Fotsch v. Eli Lilly & Co., 995 U.S. Dist. LEXIS 5227, at *3, *10 (N.D. III. 1995) (applying Sparapany, and refusing to entertain the third generation DES claims of minor plaintiffs).

ingestion of DES presents a consistent singular risk of a digestive tract injury to the grandchild of a person ingesting the drug); Sparapany v. Rexall Corp., 618 N.E.2d 1098 (Ill. Ct. App. 1993) (concluding that Illinois law precludes the imposition of a legal duty to third-generation claimants if the alleged conduct occurred prior to 1977); Grover v. Eli Lilly & Co., 591 N.E.2d 696 (Ohio 1992) (holding, on certification from the federal district court, that there is no duty to a third-generation plaintiff); Enright v. Eli Lilly & Co., 570 N.E.2d 198 (N.Y. 1991) (denying a third-generation claim premised on strict liability⁴); see also Loerch v. Eli Lilly & Co., 445 N.W.2d 560 (Minn. 1989) (summarily affirming a trial court's rejection of third generation claims). These courts were concerned with the doctrinal and public policy consequences of extending potential liability beyond the boundaries of traditional tort law. In particular, Enright and Grover, the two cases to most fully address third-generation DES claims, expressed deep concern about the potential for unlimited liability to the DES pharmaceutical manufacturers, and voiced the need to "confine liability within manageable limits." Enright, 570 N.E.2d at 203.

In considering and rejecting third-generation DES claims, courts have identified three specific problems. First, the claims have no basis in established tort doctrine because the connection between the allegedly tortious behavior and the plaintiff's injuries is too remote. Second, opening the door to third-generation plaintiffs violates public policy by creating the opportunity for unlimited liability in the number of possible litigants, and indeed in the number of potential generations who might litigate. Third, extending liability to the third generation or beyond runs in the face of public policy by deterring the research, development, and marketing of beneficial drugs. See id. at 203-04; Grover, 591 N.E.2d at 699.

⁴ The lower court in *Enright* had previously refused to allow third-generation claims premised on negligence and breach of warranty, and appellants did not challenge this decision on appeal. See Enright, 570 N.E.2d at 200.

Massachusetts Has Routinely Expressed The Concerns That Counsel Against В. Third Generation Liability.

The doctrinal and public policy concerns driving the rejection of third-generation DES claims in other jurisdictions have been prevalent and unmistakable in Massachusetts's own cases addressing DES and preconception tort claims. Together, they indicate that Massachusetts is extremely unlikely to recognize Plaintiff's third-generation DES claims.

Remoteness of third-generation claims. 1.

It is a fundamental precept of common-law negligence that a plaintiff must demonstrate, among other things, that the defendant owed a duty to the plaintiff, that injury to the plaintiff was reasonably foreseeable to the defendant, and that the defendant's alleged act was the proximate cause of the plaintiff's injury. Primus v. Galgano, 329 F.3d 236, 241 (1st Cir. 2003) (quoting Heinrich v. Sweet, 308 F.3d 48, 62-63 (1st Cir. 2002)). In a third-generation DES claim, the duty, foreseeability, and causation elements are almost impossible to satisfy, not least because the third-generation plaintiffs were never exposed to the drug. Consequently, third generation allegations must rely on "the rippling effects of DES exposure." Enright, 570 N.E.2d at 203; Grover, 591 N.E.2d at 699.

"Rippling effects," however, are not enough to impose liability. Recognizing the practical limits of foreseeability, the Grover court found it "difficult to imagine that a pharmaceutical company, during the 1940s to the 1960s, could have foreseen the effect that a drug would have not only on a patient's child, but also on that children's children." Grover, 591 N.E.2d at 698 n.1. The court therefore held explicitly that a manufacturer's duty does not extend to the third generation. "Where a pharmaceutical company prescribes drugs to a woman, the company, under ordinary circumstances, does not have a duty to her daughter's infant who will

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be conceived twenty-eight years later." Grover, 591 N.E.2d at 700. The Grover case dealt with claims very comparable to those made here.

Massachusetts has also made clear that a defendant has no duty to protect against remote, unlikely, or unforeseeable occurrences. See Lindberg v. Gilbert, 190 N.E.2d 105, 106 (Mass. 1963) ("the defendant was not bound to guard against what was only remotely likely to occur"); Glick v. Prince Italian Foods of Saugus, Inc., 514 N.E.2d 100, 102 (Mass. App. Ct. 1987) ("the court will not hold the defendant liable for all possible injury no matter how remote"); cf. Vassallo v. Baxter Healthcare Corp., 696 N.E.2d 909, 923 (Mass. 1998) (abandoning the "hindsight approach" to implied warranty of merchantability suits, which charged product manufacturers with knowledge of all risks associated with a product regardless of the state of the art, in favor of an approach that charges manufacturers with risks that are foreseeable at the time of sale or could have been discovered with testing prior to marketing). The injuries alleged in third-generation DES claims - where harm is both physically and temporally removed from actual ingestion of the drug - are precisely the kind of remote or unlikely occurrences that Massachusetts courts would find as a matter of policy to be unforeseeable.

The remoteness of third-generation claims affects not only duty and foreseeability but also causation. The Ohio Supreme Court made lack of proximate cause a specific basis for rejecting third-generation DES claims, holding that "[b]ecause of the remoteness in time and causation, [the plaintiff] does not have an independent cause of action." Grover, 591 N.E.2d at 700. Massachusetts has expressed similar concerns about remoteness saying, as example, that "as a matter of policy, it must be recognized that tort liability cannot be extended without limit." Feliciano v. Roseman Silver Co., 401 Mass. 141, 142 (1987) (refusing to extend loss of consortium claims to non-married couple). Massachusetts also, like most states, recognizes that

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2. Extending liability beyond manageable bounds.

In addition to being incompatible with traditional tort doctrine, third-generation DES claims violate public policy by inviting the extension of tort liability beyond reasonable bounds. Recognition of third generation liability increases the number of potential litigants and greatly extends the amount of time during which suits may be brought. Because a third-generation plaintiff "cannot be injured until the original patient's child bears children, the second injury will typically have occurred more than sixteen years after the ingestion of the drug." Grover, 591 N.E.2d at 699. Furthermore, because allowing third-generation claims opens the door for fourth, fifth, or successive generations - each usually 20 to 30 years apart - to bring claims based on an increasingly remote ancestor's alleged exposure, the period of liability if third-generation claims are recognized is potentially limitless. In their gate-keeping role, courts assessing DES-related claims have always drawn the line at the second generation, the last generation where direct exposure to the drug was possible. See, e.g., Enright, 570 N.E.2d at 203; Grover, 591 N.E.2d at 699.

Largely because of these same policy concerns, Massachusetts has steadfastly refused to recognize preconception torts. In Angelini, 575 N.E.2d at 42, the plaintiff sued for loss of consortium resulting from injuries his father sustained in an automobile accident. The plaintiff was in utero at the time his father was injured. The Supreme Judicial Court held that the plaintiff

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could proceed on his claim, but only because he had been conceived before the time of injury and was later born alive. *Id.* at 46. The court explained:

A child conceived after the injury, and eventually born alive, may suffer the same loss of parental consortium as a child conceived before the injury and also born alive. It may be asked, therefore, why should the latter be allowed to recover for loss of consortium and not the former? The answer is that, after a parent is negligently injured by a defendant, he or she may continue having children for many years. If no restriction is placed on the class of children who are eligible to recover for loss of parental consortium, a defendant may become liable for the loss of consortium several years, perhaps even decades, after the injury to the parent. As a matter of policy, however, it is important to limit the duration of liability.

Id. at 43 (emphasis added). Two years later, in Lareau, the federal district court barred a loss of consortium claim by a daughter who was conceived after her mother had discovered she had a brain injury, holding that "the Angelini decision necessarily bars actions by children conceived after the cause of action of the parent should have been known." See Lareau, 840 F. Supp. at 930 (citing the same policy concern about placing limits on defendant liability); McNulty v. McDowell, 613 N.E.2d 904, 907 (Mass. 1993) (refusing to recognize a duty of care running from a physician to a child not yet conceived based on the mere fact that a twenty-two year old patient is of child-bearing age in part because the physician cannot identify steps to limit liability).

Angelini, Lareau, and McNulty demonstrate that Massachusetts will not permit claims particularly preconception tort claims - that could lead to liability without end. The logic of the Angelini opinion transfers naturally to the DES context: if no restriction is placed on the class of plaintiffs who can allege injury due to DES exposure two or more generations prior, a defendant may become liable decades after the initial injury allegedly occurred. Following its own case law and that of other jurisdictions, Massachusetts is likely to dictate that the duration of DES liability must be limited to the second generation. See Angelini, 575 N.E.2d at 43. If

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Massachusetts courts refuse to recognize pre-conception torts for the immediate, second generation, surely they will not recognize pre-conception torts for the next, third generation.

The Supreme Judicial Court recently employed analogous reasoning in barring minor plaintiffs from suing their own mothers for injuries negligently inflicted while they were in utero. Remy v. MacDonald involved a minor plaintiff who brought suit against her mother for chronic respiratory injuries stemming from an emergency caesarian section necessitated by her mother's negligent operation of an automobile. 801 N.E.2d 260, 262 (Mass. 2004). The Supreme Judicial Court imposed a blanket bar on such suits citing several doctrinal and policy concerns. Foremost among those concerns was the fact that "recognizing a pregnant woman's legal duty of care in negligence to her unborn child would present an almost unlimited number of circumstances that would likely give rise to litigations." Remy, 801 N.E.2d at 263. The same concern about boundless opportunities for litigation stemming from a stale injury that led the Supreme Judicial Court to reject liability in Angelini and Remy would lead it to reject third generation DES claims as well.

3. Deterring the manufacture of beneficial drugs.

Recognizing third generation liability will also have detrimental effects on the research and development of new and useful drugs. As the Enright court explained, "public policy favors the availability of prescription drugs even though most carry some risks [W]e are aware of the dangers of over-deterrence - the possibility that research will be discouraged or beneficial drugs withheld from the market. These dangers are magnified in this context, where we are asked to recognize a legal duty toward generations not yet conceived." 570 N.E.2d at 204.

The Enright court's concern about over-deterrence is not unique. Indeed, the chilling effect that unwarranted extensions of tort liability have on research and development of useful products has long been recognized. See, e.g., P.W. Huber, Liability: The Legal Revolution and

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[T]he ultimate cost of product liability is not usually seen in the closing of existing factories, but rather in research and development not pursued, new technologies not developed, new products not introduced, new factories not built. and new jobs not created.

Blankenship v. General Motors Corp., 406 S.E.2d 781, 783 n.4 (W. Va. 1991) (citing E.P. McGuire, The Impact of Product Liability, Conference Board Report No. 908, at p. 28, Table 30 (1988)) (emphasis in original). Sharing these concerns, courts have routinely refused to extend product liability beyond traditional limits. See, e.g., Browning-Ferris Indus. of Vermont, Inc. v. Kelco Disposal, Inc., 492 U.S. 257, 282 (1989) (O'Connor, J., concurring and dissenting) (noting that the threat of punitive damage awards "has a detrimental effect on the research and development of new products"); Conafay v. Wyeth Labs., 1985 U.S. Dist. LEXIS 21618 at *8-9 (D.D.C. 1985) (recognizing that imposing strict liability in cases involving drugs "would chill if not smother the research, development, production and marketing of new prescription or experimental drugs necessary to alleviate or cure the ills to which all persons are subject"); Pollard v. Ashby, 793 S.W.2d 394, 399 (Mo. Ct. App. 1989) (determining that "withholding a drug from the market ... until scientific skill and knowledge advanced so that additional dangerous side effects might be revealed ... would not serve the public interest").

Massachusetts has explicitly cabined potential liability in DES cases so as not to deter research and development. In Payton v. Abbott Laboratories, 437 N.E.2d 171 (Mass. 1982), the Supreme Judicial Court refused to impose market share liability on DES manufacturers, concluding that "[p]ublic policy favors the development and marketing of new and more efficacious drugs.... Imposition of such broad liability could have a deleterious effect on the development and marketing of new drugs, especially those marketed generically." Payton, 437

FHBoston/1073076.5 - 11 - N.E.2d at 189-90. To make the point clear, the court added, "[i]ndeed, if a cure for clear-cell adenocarcinoma lies in the development and manufacture of some new drug, imposing market share liability might prevent the marketing of a cure for the very cancer threatening the plaintiffs." Id. at 190 n.18.

Given its stated policy of declining to extend tort liability where it would detrimentally affect the research and development of beneficial drugs, Massachusetts is unlikely to deviate from current law and permit third-generation claims that by definition extend tort liability beyond traditional bounds.

C. The Recognition Of Certain Preconception Torts In Other Jurisdictions Are Distinguishable And Are Not Applicable To Massachusetts Law.

No appellate court in any jurisdiction has explicitly permitted a third-generation DES claim to go forward. Some jurisdictions have allowed certain other preconception tort claims; however, these decisions do not predict that Massachusetts would recognize a third-generation DES claim.

First, as Angelini and its progeny demonstrate, Massachusetts has rejected causes of action based on preconception torts and there is nothing to indicate that it would contravene its own longstanding jurisprudence. The clear policy in Massachusetts is not to permit claims by plaintiffs who were not conceived when the alleged tortious activity occurred. In McNulty v. McDowell, 613 N.E.2d 904 (Mass. 1993), the Supreme Judicial Court affirmed judgment for the defendant doctor on the ground that the physician owed no duty to the plaintiff who was not conceived at the time of the allegedly negligent failure to vaccinate her mother against rubella. The court did, however, take the occasion to muse on circumstances in which a doctor might acquire a duty to a future child. McNulty, 613 N.E.2d at 907-08. This dicta dealt with hypotheticals about the immediate patient's children; policy concerns about extension of liability

FHBoston/1073076.5 - 12 - to the children of children of the women who received DES raise many additional issues. Affirmation of the judgment in McNulty, then, means that it is all the less likely that Massachusetts would leap to approving claims on behalf of a person not only un-conceived at the time of the wrongful act but born to a person who was herself not born at the time of the wrongful act, the marketing of a prescription drug with an allegedly deficient warning.

Second, the one state that has impliedly allowed preconception DES cases to go forward, Illinois, has also expressly rejected third generation claims. See Sparapany, 618 N.E.2d at 1101 (concluding that Illinois law precludes the imposition of a legal duty to third-generation claimants if the alleged conduct occurred prior to 1977). In Bowe v. Abbott Labs., 608 N.E.2d 223 (Ill. Ct. App. 1992), the plaintiffs - including a third-generation plaintiff - brought suit against a DES pharmaceutical manufacturer under a theory of market share liability. After the Illinois Supreme Court rejected market share liability in the state, the plaintiffs moved to amend their complaint to allege alternative liability. Id. at 225. The trial court denied the motion but the Illinois Court of Appeals reversed and allowed filing of the first amended complaint. *Id.* at 229. Bowe involved a case at the earliest stages of litigation, and the court based its decision entirely on procedural considerations related to amending the complaint, the alternative liability issue. The third-generation claim was not discussed at all.

In McMahon v. Eli Lilly & Co., 774 F.2d 830 (7th Cir. 1985), the appellate court reversed a District Court for the Northern District of Illinois grant of a directed verdict for defendant on the grounds (1) that the second-generation plaintiff failed to make a prima facie case showing that Lilly manufactured the DES her mother took, and (2) that Lilly had no duty to the plaintiffs because any injuries to the second generation were unforeseeable in 1955, when the secondgeneration plaintiff's mother took DES. Id. at 832. The Seventh Circuit reversed and remanded,

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holding that both issues were for the jury. While a third generation claimant appears in the caption, the court never explicitly considered the viability of a third-generation claim. Eight years later, the Illinois Supreme Court expressly considered and rejected a third-generation DES claim. Sparapany, 618 N.E.2d at 1101.

Third, the preconception torts that are allowed outside Massachusetts have invariably involved second generation plaintiffs, clear causation, and no risk of unlimited liability. In contrast, DES claims in particular present not merely preconception but inter-generational issues of unforeseeability, remoteness in causation, and prevention of unlimited or perpetual liability.

For example, cases allowing causes of action based on Rh sensitization - the most commonly recognized preconception tort - simply do not address the doctrinal and policy concerns present in third-generation DES cases. In Renslow v. Mennonite Hospital, 367 N.E.2d 1250, 1255 (Ill. 1977), for example, the Illinois Supreme Court called the case before it "clearly distinguishable" from those where "successive generations of plaintiffs complain against a single defendant for harm caused by genetic damage done [to] an ancestor..." Id. The basis of distinction was the fact that "[i]t has been...long known that the Rh-positive fetus of an Rhnegative woman previously sensitized is "at high risk." See id. at 1253 (citing S. Robbins, Pathologic Basis of Disease 557 (1974)). Contrast this with the fact that researchers of great distinction have yet to find any definitive causal link between a mother's in utero exposure to DES and physical, mental, or reproductive abnormalities in their children. See e.g. R. Kaufman, E. Adams, Findings in Female Offspring of Women Exposed In Utero to Diethylstilbestrol 197 (2002) (concluding that "the absence of abnormalities in the lower genital tract in thirdgeneration women compared with the high frequency of these abnormalities in their mothers suggests that third-generation carryover effects of in utero DES exposure are unlikely").

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The same distinctions arise in *Monusko v. Postle*, 437 N.W.2d 367 (Mich. Ct. App. 1989), in which a second-generation plaintiff brought suit against her mother's doctor, alleging injury because a doctor had negligently failed to administer a rubella test to her mother. The court held that the plaintiff's claim could proceed, but precisely because the causal connection was not in doubt: "We emphasize the direct connection between the [rubella] test and immunization procedure and the harm in this case." Id. at 370. Furthermore, there was no risk of unlimited or perpetual liability, because the injuries at issue occur only in the second generation and only arise when the mother contracts rubella during her pregnancy. *Id.* at 368. Where courts have recognized pre-conception torts, they consistently emphasize clear causal patterns and the foreseeability of injury. These factors simply are not the hallmark of DES thirdgeneration claims.

Distinctions are also obvious in the two cases permitting preconception tort claims based on faulty contraceptives. In Wells v. Ortho Pharmaceutical Corp., 615 F. Supp. 262, 268 (N.D. Ga. 1985), the second-generation plaintiff alleged that her parents' use of defendant's spermicidal jelly just prior to her conception had caused birth defects and other injuries. The substance of plaintiff's allegations were that the active ingredient in the contraceptive caused defects at some stage of her embryonic or fetal development - in other words, that she had been affected directly by the product. Id. In third generation DES cases, plaintiffs do not allege that any active ingredient of DES affects the plaintiff, but rather that the uterine abnormalities resulting from the mother's exposure to DES have injurious effects. See Complaint ¶ 26 (alleging that Minor Plaintiffs were born prematurely "because of [their] mother's DES-injured birth uterus..."). Without direct causal link between DES and their claimed injuries, third

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generation DES plaintiffs are one step removed from the kind of preconception tort recognized in Wells.

Finally, two cases permitting a preconception cause of action based on negligent performance of a Caesarian section on the plaintiff's mother are also distinguishable. Secondgeneration plaintiffs alleged in both cases that they had sustained injury in utero as a result of earlier negligent surgery that had caused their mother's uterus to rupture during pregnancy. See Bergstreser v. Mitchell, 577 F.2d 22 (8th Cir. 1978) (construing Missouri law); Martin v. St. John Hosp. & Med. Ctr. Corp., 517 N.W.2d 787 (Mich. Ct. App. 1994). Massachusetts has already held, however, that a plaintiff may not raise a claim based on injuries to the parent before the plaintiff was conceived. Lareau, 840 F. Supp. at 930; Angelini, 575 N.E.2d at 43. The holdings of Bergstreser and Martin, therefore, directly contradict established Massachusetts law.

CONCLUSION

Massachusetts does not recognize preconception torts. In the few jurisdictions where preconception torts have been recognized, they invariably involve second-generation plaintiffs, straightforward patterns of causation, and no risk of perpetual liability. By contrast, thirdgeneration DES claims have none of these characteristics and have been rejected explicitly because of these distinctions. The case-specific reasoning permitting other forms of preconception torts in some other states, then, supports the conclusion that Massachusetts would reject third-generation DES causes of action.

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REQUEST FOR ORAL ARGUMENT

Pursuant to LCvR 7.1(D), Lilly requests a hearing on its Motion for Partial Summary Judgment.

Respectfully submitted,

ELI LILLY AND COMPANY

/s/ James J. Dillon

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